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14. ABSTRACT A total of 39 specimens have been submitted to Precision for this study. Twenty (20) subjects have been enrolled in this study to date. Tissue was submitted at the time of a diagnostic core biopsy procedure for nineteen (19) subjects. Seventeen (17) subjects' results did not qualify them for the main research study. Two (2) subjects' pathology reports and enrollment on the study is pending. One (1) subject was discontinued for an adverse experience on her SOC chemotherapy. There are no safety issues (anticipated or unanticipated) to report for a study-related procedure. A total of nine (9) principal investigators have now been approved by the DoD to participate in this study. Precision is working with US Oncology to initiate a group of research sites to help boost enrollment. An additional 12 sites are in varying phases of study start-up. Precision held its first investigator meeting in conjunction with the ASBS Conference in Las Vegas, NV, on May 1, 2010. Subject screening and monitoring activities are ongoing. Strategies for increasing enrollment are being implemented.					
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## Table of Contents

	<u>Page</u>
Introduction.....	4
Overall Progress .....	4
Problem Areas.....	8
Work to be Performed in Next Quarter .....	9
Key Research Accomplishments.....	9
Reportable Outcomes.....	9
Conclusion .....	9
References .....	9
Supporting Data .....	9

## **Introduction**

The objective of this study is to develop a biomarker to predict pathological complete response in women treated with neoadjuvant chemotherapy for breast cancer. Such a biomarker would assist physicians in selecting the most effective chemotherapy for the individual patient. The anticipated biomarker will take into account clinical factors (such as tumor stage, tumor size, and age), phenotypic characteristics of the tumor (determined by pathological immunohistochemistry and *ex vivo* chemoresponse assay), and genotypic characteristics of the tumor and patient (determined by genomic profiling via gene expression analysis of tumor RNA). It is expected that collective consideration of all of these factors will be more predictive of patient response to therapy than any of them alone.

Approximately 224 evaluable subjects will be recruited from approximately 20 – 30 US sites. Women with measurable operable invasive breast cancer diagnosed by core needle biopsy will be eligible for this study. Additional tumor specimens will be obtained prior to the start of chemotherapy via core needle biopsies to be used for the *ex vivo* chemoresponse assay and tumor genomic analysis (gene expression), respectively.

All subjects will receive neoadjuvant chemotherapy with one of two standard of care regimens that must consist of the following agents: doxorubicin (A), cyclophosphamide (C), and a taxane (T) such as docetaxel, paclitaxel, or Abraxane (nanoparticle albumin-bound paclitaxel [nab-paclitaxel]); or, docetaxel (T) and cyclophosphamide (C). These must be administered per NCCN guidelines by the treating physician.

Upon completion of chemotherapy treatment, women will undergo lumpectomy, modified radical mastectomy or other surgical procedure determined appropriate by the investigator and at that time will be evaluated for pathological response. At the time of lumpectomy, modified radical mastectomy, or other surgical procedure, additional tumor excess may be sent to Precision Therapeutics, Inc. (Precision) for exploratory analysis if there is no pathologic complete response (pCR), if there are sufficient tumor cells to send, and if the subject agrees to have her excess tumor cells sent to Precision for this purpose.

During the subject's course of participation on the study, the treating physician will remain blinded to the results of the chemoresponse assay and genomic analysis. If it is determined there is no pCR at the time of lumpectomy, modified radical mastectomy or other surgical procedure, or if the subject's condition deteriorates while on chemotherapy and she needs to stop treatment, upon request, Precision will make available a subsequent report to the physician containing additional information about chemotherapy drugs other than ACT that may benefit future treatment decisions for the patient.

## **Overall Progress**

A total of 39 specimens have been submitted to Precision for this study. Twenty (20) eligible subjects have been enrolled in this study to date. Tissue was submitted at the time of a diagnostic core biopsy procedure for nineteen (19) subjects. Seventeen (17) subjects' results did not qualify them for the main research study; of the 17, two (2) subjects' pathology reports and enrollment on the study remains pending. One (1) subject was discontinued for an adverse experience on her SOC chemotherapy. There are no safety issues (anticipated or unanticipated) to report for a study-related procedure.

A total of nine (9) principal investigators have now been approved by the DoD to participate in this study. An additional 12 sites are in varying phases of study start-up. Two (2) investigators, Dr. Falk and Dr. Akbari do not have enough staffing resources to participate, however, have agreed to remain involved in an independent data review capacity.

The following investigators have been submitted to the DoD and modifications are being finalized to DoD-required elements in the informed consents: Dr. Boolbol, Dr. Chevinsky, and Dr. Garcia. DoD approval is expected in early Q3.

Precision successfully held its first investigator meeting at the American Society of Breast Surgeons (ASBS) Conference in Las Vegas, NV, on May 1, 2010.

***Detailed progress made between the period of June 12, 2009 – June 11, 2010***

I. Work with a total of 23 investigators remains ongoing and is detailed in the table below (*pink is approved for enrollment while green is Independent Data Review Committee member*). Several investigators have dropped out due to changes in their research staff / vacancies.

*\*In response to an enrollment lag, Precision has contacted representatives of US Oncology for additional research sites. US Oncology has received approval by their scientific committee to proceed with the study and multiple sites within the network are being surveyed to determine feasibility. Results of the number of sites we may be able to add will be known in mid-July, 2010.*

<b>Participating Sites</b>	<b>Status Update</b>
Richard Fine, MD <b>Advanced Breast Care</b> 790 Church Street, Suite 410 Marietta, GA 30060	<ul style="list-style-type: none"> <li>• Approved for enrollment by the DoD</li> <li>• Actively screening subjects</li> </ul>
Judy Tjoe, MD <b>Aurora Health Care Inc.</b> 8000 Montana Milwaukee, WI 53219 <i>*Change in PI since last quarterly report</i>	<ul style="list-style-type: none"> <li>• Contract under negotiation</li> <li>• Submission to the IRB - pending</li> <li>• Q3 2010 submission of regulatory documentation to the DoD</li> <li>• SIV will be scheduled in Q3 2010</li> </ul>
Susan Boolbol, MD <b>Beth Israel Hospital</b> 10 Union Square East, Suite 4E New York, NY 10003	<ul style="list-style-type: none"> <li>• Regulatory documentation to the DoD submitted; consent form revision requested and approval pending</li> <li>• SIV will be scheduled in Q3 2010</li> </ul>
Beth DuPree, MD <b>Bott Cancer Center at the Holy Redeemer Hospital</b> 1648 Huntingdon Pike Meadowbrook, PA 19046	<ul style="list-style-type: none"> <li>• Qualification call scheduled for March 16, 2010.</li> <li>• Contract negotiation pending</li> <li>• IRB approval pending</li> </ul>
Mark Gittleman, MD <b>Breast Care Specialists, PC</b> 250 Cetronia Road, Suite 302 Allentown, PA 18104	<ul style="list-style-type: none"> <li>• Approved for enrollment by the DoD</li> <li>• Actively screening subjects</li> </ul>

Michael Berry, MD <b>Breast Clinic of Memphis</b> 1385 West Brierbrook Road Germantown, TN 38138	<ul style="list-style-type: none"> <li>• Contract executed</li> <li>• Submission to the WIRB – pending</li> <li>• Federalwide Assurance – pending discussion with Baptist</li> </ul>
Theodore Potruch, MD <b>BreastCare</b> 2020 Goldring Ave., Suite 206 Las Vegas, NV 89106	<ul style="list-style-type: none"> <li>• Approved for enrollment by DoD</li> <li>• Actively enrolling and screening subjects</li> </ul>
John West, MD <b>BreastLink</b> 230 South Main Street, Suite 100 Orange, CA 92868	<ul style="list-style-type: none"> <li>• Approved for enrollment by the DoD</li> <li>• Actively screening subjects</li> <li>• Competing study (NSABP B-40) will be closing in June, enrollment to pick up following closure</li> </ul>
Peter Beitsch, MD <b>Cancer Solutions</b> 7777 Forest Lane, Suite C-760 Dallas, TX 75320	<ul style="list-style-type: none"> <li>• Approved for enrollment by the DoD</li> <li>• Actively enrolling and screening subjects</li> </ul>
Farin Amersi, MD <b>Cedars-Sinai Medical Center</b> 8700 Beverly Blvd. Los Angeles, CA 90048	<ul style="list-style-type: none"> <li>• Contract under negotiation</li> <li>• Submission to the IRB - pending</li> <li>• Q3 2010 submission of regulatory documentation to the DoD</li> <li>• SIV will be scheduled in Q3 2010</li> </ul>
Stephanie Akbari, MD <b>Center for Breast Health, PC</b> 1625 North George Mason Drive Suite 315 Arlington, VA 22205	<ul style="list-style-type: none"> <li>• Initiation of paperwork stalled due to limited research staff</li> <li>• Precision has offered physician a role on the Independent Data Review Committee instead of participation in the study – <i>decision is pending</i></li> </ul>
Cynthia Aks, MD <b>Downriver Comprehensive Breast Center</b> 13383 Reeck Ct Southgate, MI 48195	<ul style="list-style-type: none"> <li>• Contract under negotiation</li> <li>• Submission to the IRB - pending</li> <li>• Q3 2010 submission of regulatory documentation to the DoD</li> <li>• SIV will be scheduled in Q3 2010</li> </ul>
Walton Taylor, MD <b>Leading Edge Research, P.A.</b> 9229 LBJ Freeway Dallas, TX 75243	<ul style="list-style-type: none"> <li>• Q3 2010 submission of regulatory documentation to the DoD</li> <li>• SIV will be scheduled in Q3 2010</li> </ul>
Jeffrey Falk, MD <b>Michigan Breast Specialists</b> 19229 Mack Avenue, Suite 38 Grosse Pointe Woods, MI 48236	<ul style="list-style-type: none"> <li>• Initiation of paperwork stalled due to limited research staff</li> <li>• Precision has offered physician a role on the Independent Data Review Committee instead of participation in the study – physician has agreed to be on the committee instead of participating in the study</li> </ul>

<p>Aaron Chevinsky, MD  <b>Morristown Memorial Hospital (aka AtlanticHealth)</b>  95 Madison Avenue, Ste 304c  Morristown, NJ 07960</p>	<ul style="list-style-type: none"> <li>• Q1 2010 submission of regulatory documentation to the DoD; approval by DoD pending</li> <li>• SIV will be scheduled in Q3 2010</li> </ul>
<p>Pat Whitworth, MD  <b>Nashville Breast Center, P.C.</b>  300 20th Avenue North, Suite 401  Nashville, TN 37203</p>	<ul style="list-style-type: none"> <li>• Approved for enrollment by the DoD</li> <li>• Actively screening subjects</li> </ul>
<p>James Mackey, MD and Robin Skrine, MD  <b>Southlake Oncology</b>  1545 E. Southlake Boulevard, Suite 280  Southlake, TX 76092</p>	<ul style="list-style-type: none"> <li>• Approved for enrollment by the DoD</li> <li>• Actively screening subjects</li> </ul>
<p>Laura Lawson, MD  <b>St. Thomas Research Institute</b>  4230 Harding Road  Nashville, TN 37205</p>	<ul style="list-style-type: none"> <li>• Approved for enrollment by the DoD</li> <li>• Actively screening subjects</li> </ul>
<p>Adam Brufsky, MD  <b>University of Pittsburgh Medical Center / University of Pittsburgh Cancer Institute / Magee Women's Hospital of UPMC</b>  300 Halket Street  Pittsburgh, PA 15213-3180</p>	<ul style="list-style-type: none"> <li>• Q3 2010 submission of regulatory documentation to the DoD</li> <li>• SIV will be scheduled in Q3 2010</li> </ul>
<p>William Dooley, MD  <b>University of Oklahoma Health Sciences Center</b>  1000 Stanton L. Young Blvd., LIB 121  Oklahoma City, OK 73117</p>	<ul style="list-style-type: none"> <li>• Q3 2010 submission of regulatory documentation to the DoD</li> <li>• SIV will be scheduled in Q3 2010</li> </ul>
<p>Agustin Garcia, MD  <b>University of Southern California / Norris Comprehensive Cancer Center</b>  1441 Eastlake Avenue  Los Angeles, CA 90033</p>	<ul style="list-style-type: none"> <li>• Site under significant, unanticipated delays due to consenting issues</li> <li>• Q2 submission of regulatory documentation to the DoD; approval pending</li> <li>• SIV will be scheduled in Q3 2010</li> </ul>
<p>Michael Danso, MD  <b>US Oncology Network</b>  Virginia Oncology Associates  5900 Lake Wright Dr  Norfolk, VA 23502</p>	<ul style="list-style-type: none"> <li>• Number of satellite sites TBD</li> <li>• Contract under negotiation</li> <li>• Submission to the IRB - pending</li> <li>• Q3 2010 submission of regulatory documentation to the DoD</li> <li>• SIV will be scheduled in Q3 2010</li> </ul>
<p>Ekaterini Tsiapali, MD  <b>Women and Infants Hospital of RI</b>  101 Dudley Street  Providence, RI 02905</p>	<ul style="list-style-type: none"> <li>• Approved for enrollment by the DoD</li> <li>• Actively screening subjects</li> </ul>

II. On May 1, 2010, 12:15 – 1:30 pm, Precision held its first PT-304 Investigator Luncheon Meeting in conjunction with the ASBS Conference in Las Vegas, NV. The following investigators and coordinators were in attendance:

Stephanie Akbari, MD and Molly Sebastian, MD (practice partners)  
Cynthia Aks, MD  
Farin Amersi, MD  
Peter Beitsch, MD  
Michael Berry, MD  
Susan Boolbol, MD  
Lisa Curcio, MD, invited breast surgeon guest  
William Dooley, MD and study coordinator Jeanene Parker  
Jeffrey Falk, MD, data review committee member  
Shawna Keen and Serena Venezuela, study coordinators of Theodore Potruch, MD  
Trish Kelly, MD (Mark Gittleman's practice partner)  
Laura Lawson, MD

Other investigators either had a scheduling conflict or were unable to attend the ASBS conference.

Overall, the presentation and discussion during the investigator meeting was positive. Both Precision and some study sites are faced with challenges including, 1) conforming to DoD-approved template consent forms without customizations required by local IRBs, 2) getting through the DoD review approval process when first submitted, 3) waiting for a competing trial to close (NSABP B-40), and 4) waiting through the protracted IRB, budget and contract review and approval process.

Highlights of the study were reviewed, including: total enrollment and general statistics, number of active sites, tissue taken at diagnostic procedure, tissue taken post-diagnosis, and types of screen failures. Strategies for extracting the best biopsy specimens for this study were thoroughly reviewed. Overall, the investigators' feedback was encouraging for ramping up accrual. Precision remains committed to accelerating enrollment rates to reach the 280 accrual goal, hopefully by year's end. See Attachment 1 for anticipated accrual rates.

III. Amendment #1 to the protocol (version date January 27, 2010) is implemented at 9 research sites and all other sites will be initiating this current version of the study upon activation.

## **Problem Areas**

I. Meeting enrollment benchmarks for active sites. Precision continues to work with sites to help meet the monthly accrual targets. A large neoadjuvant breast study (NSABP B-40) which will be closing to accrual June 30, 2010, is a competing trial for four (4) of our sites. Their enrollment onto the PT-304 study is expected to pick up following the completion of that study.

II. The IRB and contracting phases at several sites has been a very long process (exceeding more than 9 months): Dr. Berry, Dr. Garcia, Dr. Dupree, Dr. Brufsky, and Dr. Dooley.

III. DoD review of regulatory paperwork from research sites: Precision's latitude for allowing for local IRB policies to prevail in consent forms is not the same as the DoD. Research sites have had to re-review and modify consent forms per more strict DoD standards detailed in the

protocol Evaluation Forms (PEFs). Three (3) sites have been significantly delayed because of consent form issues: Dr. Boolbol, Dr. Garcia, and Dr. Chevinsky.

Precision has identified those problem areas in the consent forms and will work with the other sites to avoid future issues with the DoD reviews and approvals.

### **Work to be Performed in Next Quarter**

I. Paperwork for Dr. Brufsky, Dr. Garcia, Dr. Tjoe, Dr. Berry, Dr. Amersi, Dr. Taylor, Dr. DuPree, and Dr. Dooley will be obtained and submitted to the DoD for final review and approval. A group of network sites under US Oncology is expected to work toward activation under Dr. Danso.

II. We will continue to schedule Site Initiation Visits (SIVs) to train sites on both the protocol requirements and the use of MedNet's EDC system, and conduct Interim Monitoring Visits (IMVs) to monitor the data on subjects enrolled in the study.

III. We will continue to work with MedNet to test and approve necessary changes to the database to reflect the most current version of the protocol and case report forms. A very large release is scheduled for July, 2010.

IV. We will continue to monitor the obstacles or issues of the study, assess tissue collection procedures and viability of tissue from study sites, and make strides in accruing eligible subjects in this study.

### **Key Research Accomplishments**

Not applicable

### **Reportable Outcomes**

Not applicable

### **Conclusion**

Not applicable

### **References**

Not applicable

### **Supporting Data**

Not applicable

ATTACHMENT 1

Anticipated Accrual from May 14, 2010 – December 31, 2010

*\*Pink indicates currently activated sites and yellow indicates sites submitted to DoD pending approval*

Participating Sites	Status Update	Accrual by May 2010	Accrual from June – December 2010	Total Accrual
Richard Fine, MD Advanced Breast Care	<ul style="list-style-type: none"> <li>January -- May Accrual 0 subjects</li> <li>June -- December Accrual Anticipated at 7 subjects for a total of <b>7 subjects</b></li> </ul>	0	7	7
Judy Tjoe, MD Aurora Health Care Inc.	<ul style="list-style-type: none"> <li>Q3 Approval by DoD Expected</li> <li>July through December Accrual Anticipated for a total of <b>6 subjects</b></li> </ul>	N/A	6	6
Susan Boolbol, MD Beth Israel Hospital	<ul style="list-style-type: none"> <li>Q3 Approval by DoD Expected</li> <li>June -- December Accrual Anticipated at 7 subjects for a total of <b>7 subjects</b></li> </ul>	N/A	7	7
Beth DuPree, MD Bott Cancer Center at the Holy Redeemer	<ul style="list-style-type: none"> <li>Q3 Approval by DoD Expected</li> <li>June -- December Accrual Anticipated at 8 subjects for a total of <b>8 subjects</b></li> </ul>	N/A	8	8
Mark Gittleman, MD Breast Care Specialists, PC	<ul style="list-style-type: none"> <li>January -- May Accrual 0 subjects</li> <li>June -- December Accrual Anticipated at 14 subjects for a total of <b>14 subjects</b></li> </ul>	0	14	14
Michael Berry, MD Breast Clinic of Memphis	<ul style="list-style-type: none"> <li>Q3 Approval by DoD Expected</li> <li>July through December Accrual Anticipated for a total of <b>6 subjects</b></li> </ul>	N/A	6	6

Theodore Potruch, MD BreastCare	<ul style="list-style-type: none"> <li>• Through December 2009 10 subjects</li> <li>• January -- May Accrual 20 Subjects</li> <li>• June -- December Accrual Anticipated at 28 subjects for a total of <b>48 subjects</b></li> </ul>	20	28	<b>48</b>
John West, MD BreastLink	<ul style="list-style-type: none"> <li>• January -- May Accrual 0 subjects</li> <li>• June -- December Accrual Anticipated at 14 subjects for a total of <b>14 subjects</b></li> </ul>	0	14	<b>14</b>
Peter Beitsch, MD Cancer Solutions	<ul style="list-style-type: none"> <li>• January -- May Accrual Anticipated at 4 subjects</li> <li>• June -- December Accrual Anticipated at 16 subjects for a total of <b>20 subjects</b></li> </ul>	4	16	<b>20</b>
Farin Amersi, MD Cedars-Sinai Medical Center	<ul style="list-style-type: none"> <li>• Q3 Approval by DoD Expected</li> <li>• July through December Accrual Anticipated for a total of <b>10 subjects</b></li> </ul>	N/A	10	<b>10</b>
Cynthia Aks, MD Downriver Comprehensive Breast Center	<ul style="list-style-type: none"> <li>• Q3 Approval by DoD Expected</li> <li>• September through December Accrual Anticipated for a total of <b>4 subjects</b></li> </ul>	N/A	4	<b>4</b>
Walton Taylor, MD Leading Edge Research, P.A.	<ul style="list-style-type: none"> <li>• Q3 Approval by DoD Expected</li> <li>• Accrual Anticipated at 6 subjects for a total of <b>6 subjects</b></li> </ul>	N/A	6	<b>6</b>
Aaron Chevinsky, MD Morristown Memorial Hospital (Atlantic Health)	<ul style="list-style-type: none"> <li>• Q3 Approval by DoD Expected</li> <li>• June -- December Accrual Anticipated at 10 subjects for a total of <b>10 subjects</b></li> </ul>	N/A	10	<b>10</b>
Pat Whitworth, MD Nashville Breast Center, P.C.	<ul style="list-style-type: none"> <li>• January -- May Accrual Anticipated at 4 subjects</li> <li>• June -- December Accrual Anticipated at 16 subjects for a total of <b>20 subjects</b></li> </ul>	4	16	<b>20</b>

James Mackey, MD and Robin Skrine, MD	<ul style="list-style-type: none"> <li>• January -- May Accrual Anticipated at 2 subjects</li> <li>• June -- December Accrual Anticipated at 10 subjects for a total of <b>10 subjects</b></li> </ul>	0	10	<b>10</b>
Laura Lawson, MD St. Thomas Research Institute	<ul style="list-style-type: none"> <li>• February -- May Accrual Anticipated at 2 subjects</li> <li>• June -- December Accrual Anticipated at 10 subjects for a total of <b>10 subjects</b></li> </ul>	0	10	<b>10</b>
Adam Brufsky, MD University of Pittsburgh Medical Center / University of Pittsburgh Cancer Institute / Magee Women's Hospital of UPMC	<ul style="list-style-type: none"> <li>• Q3 Approval by DoD Expected</li> <li>• June -- December Accrual Anticipated at 15 subjects for a total of <b>15 subjects</b></li> </ul>	N/A	15	<b>15</b>
William Dooley, MD University of Oklahoma Health Sciences Center	<ul style="list-style-type: none"> <li>• Q3 Approval by DoD Expected</li> <li>• July through December Accrual Anticipated for a total of <b>6 subjects</b></li> </ul>	N/A	6	<b>6</b>
Agustin Garcia, MD USC / Norris Comprehensive Cancer Center	<ul style="list-style-type: none"> <li>• Q3 Approval by DoD Expected</li> <li>• June -- December Accrual Anticipated at 12 subjects for a total of <b>12 subjects</b></li> </ul>	N/A	12	<b>12</b>
Michael Danso, MD, US Oncology Network	<ul style="list-style-type: none"> <li>• Q3 Approval by DoD Expected</li> <li>• September through December Accrual Anticipated for a total of <b>37 subjects</b></li> </ul>	N/A	37	<b>37</b>
Ekaterini Tsiapali, MD Women and Infants Hospital of RI	<ul style="list-style-type: none"> <li>• February -- May Accrual 0 subjects</li> <li>• June -- December Accrual Anticipated at 10 subjects for a total of <b>10 subjects</b></li> </ul>	0	10	<b>10</b>
<b>TOTALS</b>		<b>28</b>	<b>252</b>	<b>280</b>